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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,057	06/26/2007	Michelle Alfa	81190-3002	5997

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,057	ALFA, MICHELLE	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/25/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

4. The information disclosure statement filed on 6/25/2007 has been considered. An initialed copy is enclosed.

Election/Restrictions

5. Applicant's election of Group III claims 15-21 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Examiner will consider claims 22-25 for examination. Therefore Group III is claims 15-25.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 15, 17, 19-21, 23-25 rejected under 35 U.S.C. 102(b) as being anticipated by Bostwick et al WO 00/24266 Date May 5, 2000.

Claims 15, 17, 19-21, 23-25 are drawn to a method of treating *Clostridium difficile* infection comprising administering to a patient in need thereof an effective dose of a pharmaceutical composition comprising: polyclonal antibodies directed against at least one enteric pathogen; and a probiotic.

Bostwick et al teach compositions including a soy product and an active immunoglobulin for nutrition and overall health benefits to humans and animals. The compositions of the invention can be in the form of a tablet, capsule, and liquid, functional food, beverage or special use food (see abstract). Bostwick et al teach a composition can include yogurt cultures to replenish or enhance normal gastrointestinal flora and that bacterial organisms suitable for yogurt culture include, bacteria of the *Lactobacillus* and *Bifidobacterium* genera (see abstract, claims, pgs. 1-18). Therefore the method comprising the pharmaceutical composition of Bostwick et al inherently teaches a pharmaceutical composition comprising an oligosaccharide. Bostwick et al teach that active immunoglobulins can be collected from a human or animal that has been specifically immunized against antigenic targets *Clostridium difficile*, toxins (*C. difficile* toxins A and B (see pg. 12).

Thus Bostwick et al teach a method of treating *Clostridium difficile* infection comprising administering to a patient in need thereof an effective dose of a pharmaceutical composition comprising: polyclonal antibodies directed against at least one enteric pathogen; and a probiotic, wherein the probiotic is *Bifidobacterium*, or *Lactobacillus*, wherein the pharmaceutical composition is microencapsulated, wherein the polyclonal antibodies are raised against more than one antigen derived from *Clostridium difficile*, wherein the pharmaceutical composition is in combination with a suitable food product, wherein the food product is a yogurt or a yogurt-based drink, wherein the antigen is *Clostridium difficile* Toxin A and *Clostridium difficile* Toxin B.

7. Claims 15, 17-18 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Chandler et al WO 97/20577 Date June 12, 1997.

Claims 15, 17-18 and 20 are drawn to a method of treating Clostridium difficile infection comprising administering to a patient in need thereof an effective dose of a pharmaceutical composition comprising: polyclonal antibodies directed against at least one enteric pathogen; and a probiotic.

Chandler et al teach to a method of treating *Clostridium difficile* infection comprising administering to a patient in need thereof an effective dose of a

pharmaceutical composition comprising: polyclonal antibodies directed against at least one enteric pathogen; and a probiotic, wherein the probiotic is *Bifidobacterium, Enterococcus, or Lactobacillus*, wherein the polyclonal antibodies are egg yolk antibodies (see pages abstract, 5-8). Chandler et al teach that administration includes lozenges or other tablets thus Chandler et al teach a method, wherein the pharmaceutical composition is microencapsulated (see pg. 7).

8. Claims 15 and 17-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Bostwick et al WO 00/24266 in view of US Patent 6,969,520 Thomas et al Date November 29, 2005 Date filed December 16, 2003.

Claims 15 and 17-25 are drawn to a method of treating *Clostridium difficile* infection comprising administering to a patient in need thereof an effective dose of a pharmaceutical composition comprising: polyclonal antibodies directed against at least one enteric pathogen; and a probiotic.

Bostwick is relied upon as set forth supra. However Bostwick et al does not teach a method, wherein the *Clostridium difficile* associated diarrhea (CDAD).

Thomas et al teach invention provides active and passive immunization methods for preventing and treating *Clostridium difficile* infection, which involve administration of C. difficile toxin-neutralizing polyclonal immune globulin with a patient that has or is at risk of developing recurrent *Clostridium difficile* associated diarrhea.

It would have been prima facie obvious at the time the invention was made to modify the invention by treating *Clostridium difficile* associated diarrhea as taught by Thomas et al with the method as taught by Bostwick et al because both Thomas et al and Bostwick et al teach methods of treating *Clostridium difficile* by administering polyclonal antibodies.

Status of the Claims

9. No claims are allowed.

Claims 15 and 17-25 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie
Examiner
Art Unit 1645

/Nina A Archie/
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